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09/945,505	08/31/2001	Alison E. Anastasio	MWH-30US	3529

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GENAISSANCE PHARMACEUTICALS
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EXAMINER	
GOLDBERG, JEANINE ANNE	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/945,505	ANASTASIO ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *13-21,24,25,28 and 34-45* is/are pending in the application.

4a) Of the above claim(s) *36-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-19,24,28 and 40-43* is/are rejected.

7)☒ Claim(s) *20,21,25,34 -35, 44-45* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed January 23, 2003. Currently, claims 13-21, 24-25, 28, 34-45 are pending. Claims 36-39 have been withdrawn as drawn to non-elected subject matter.

2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.

3. Any objections and rejections not reiterated below are hereby withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 18, 19, 24 and Newly Added Claim 40-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 24 and 40-41 are drawn to nucleic acids minimally containing 15 nucleotides from SEQ ID NO: 1. Claims 18-19, 42 are drawn to oligonucleotides

designed to haplotype each of PS's listed. Claim 42 requires the oligonucleotides to be at least 15 nucleotides in length.

The claims broadly encompass nucleic acid fragments, cDNA, and genomic nucleic acids which minimally comprise 15 nucleotides from the recited positions, namely, PS1, PS4, PS12, PS14, PS15, PS17 and PS18 of SEQ ID NO: 1. The claim requires a partial structure of 15 nucleotides from SEQ ID NO: 1. The claim therefore broadly encompasses additional variants, splice variants, mutations, homologues, sequences from additional species.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2b 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2b 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...' required a precise definition, such as by structure, formula, chemical name, or physical properties', not a

mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, Applicant has defined only a fragment of a nucleic acid sequence. The claims read on TNFRSF1A variants, splice variants, mutations, homologues, sequences from additional species. For example, the post filing date art teaches additional mutations and variations within the FNFRSF1A gene which cause associated periodic syndrome. Specifically, Aganna (Arthritis & Rheumatism, Vol.. 46, No. 1, page 245-249, January 2002) teaches a transition encoding a Cys70Arg variant in exon 3. The instant specification does not teach a variation in exon 3 changing the coding sequence from C70R. Moreover, Aganna et al (Eur. J. Human Genetics, Vol. 9, pages 63-66, 2001) teaches a mutation in the TNFRSF1A gene which reduced plasma TNFRSF1A levels at R92P. The instant specification fails to teach a mutation of R92P. Aksentijevich et al (Am. J. Hum. Genet. Vol. 69, pages 301-314, 2001) teaches four novel mutations in the TNFRSF1A gene and a splice-acceptor site upstream of exon 3 (abstract). As seen in Figure 3, an aberrantly spliced transcript begins prior to exon 3, thus generating a variant cDNA and protein sequence. The instant specification does not contemplate or teach aberrantly spliced transcripts. Therefore, based upon the post-filing date art, the instant claims encompass a large number embodiments within the scope of the claim which have not been described. The knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. The nature of alleles is that they are variant

structures, and in the present state of the art the structure of one does not provide guidance to the structure of others. The common attributes of the genus are not described. One of skill in the art would conclude that applicant was not in possession of the claimed genus because the description of the isogenes is not representative of the genus and is insufficient to support the claim.

With respect to Claim 18-19, 42, the claims do not provide any particular structure of the oligonucleotides. The oligonucleotides may be from SEQ ID NO: 1 or the oligonucleotides may be any other sequence which is from a splice variant, homologue or mutated sequence. There is no requirement that the oligonucleotides have any particular structure. The set of oligonucleotides may be a primer set which flanks the entire gene; a primer set from within an undisclosed region; a primer set from a sequence which has not been disclosed. For the reasons provided above with respect to fragments comprising 15 mers, the rejection is also applicable to the instant claims.

Response to Arguments

The response traverses the rejection. The response asserts that the claim have been amended to require that the fragment include one of seven specific polymorphisms and a fragment of the particular isogene of Claim 20. This argument has been reviewed but is not convincing because the claim remains drawn to a fragment comprising at least 15 contiguous nucleotides. The claims are not drawn to fragments consisting of particular sequences. The claim is drawn to a fragment which

may be embedded within a larger sequence. Thus the claims remain drawn to homologues, variants and splice variants which have not been described.

Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-17, 28, 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A1) Claims 13-17 are indefinite over the recitation "several nucleotides downstream." The term "several" in claim 13 is a relative term which renders the claim indefinite. The term "several" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. SEQID NO: 1 is 20,519 nucleotides in length. Several in terms of this large sequence is not clear. Several is more than 1, but not as large as the full sequence. The metes and bounds of "several" as it relates to the instant claims is not clear.

B1) Claims 15, 17 are indefinite over the recitation "a sequence terminating in one of SEQ ID NO: 11-38." It is unclear whether the claim means that SEQ ID NO: 11-38 are the last nucleotides of the oligonucleotide or whether the sequence is merely more downstream than upstream. The "termination" of a sequence is different than a sequence terminating in SEQ ID NO: 11, for example. In the later, SEQ ID NO: 11 does

not need to include the last nucleotide of the oligonucleotide, but rather would just indicate that SEQ ID NO: 11 is more downstream than upstream. Alternatively, it is unlclear whether the nucleic acid may terminate at the 5' end or the 3' end of the oligonucleotide with one of these sequences. The claim does not require that the 3'terminus is SEQ ID NO: 11-38. It is unclear which interpretation is intended by the instant claims. The specification indicates that a preferred oligonucleotide primer for detecting TNFRSF1A gene polymorphisms by primer extension terminates in a nucleotide sequence selected from SEQ ID NO: 25-38." This is not the same scope as the claim written.

C1) Claims 28, 42 are indefinite over the recitation "that includes adenine substituted at a position corresponding to nucleotide 935" because it is unclear whether the 15 contiguous nucleotides corresponds to nucleotide 935 or whether the fragments spans the nucleotide. The recitation "includes" does not require a particular position for the fragment, but rather merely provides that the fragment includes adenine. The claim may be easily amended to require that the 15 contiguous nucleotides spans nucleotide 935, wherein nucleotide 935 is an adenine.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 13-14, 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Nandabalan et al (WO 00/50436, August 2000).

It is noted that the inventorship of WO 00/50436 and the instant application are different.

Nandabalan et al. (herein referred to as Nandabalan) teaches polymorphisms and haplotypes within the TNFRSF1A gene (also referred to as TNFR1 gene). Nandabalan teaches PCR primer pairs located in various regions of the gene. SEQ ID NO: 78 is upstream of PS4, PS12, PS14, PS15, PS17 and PS18. Thus, SEQ ID NO: 78 of Nandabalan is an isolated oligonucleotide which may be used to amplify the gene and used to detect polymorphisms at positions PS4, PS12, PS14, PS15, PS17 and PS18 (limitations of Claim 13). The primer of Nandabalan specifically hybridizes to an allele of the TNFRSF1A gene at a region containing the polymorphic site. For example, the primer hybridizes to the region upstream of exon 1 where PS4 is located, therefore, the primer hybridizes to the same region (limitations of Claim 14). The oligonucleotide is consider a primer, therefore, nucleic acid is a primer extension oligonucleotides (limitations of Claim 16).

Response to Arguments

The response traverses the rejection. The response asserts that Claim 13 has been amended to overcome the rejections. Specifically, the response asserts that Nandabalan's primers do not include any of the polymorphic sites are located more than several nucleotides away from the polymorphic sites. As noted below in the 112/2nd, "several" is a relative term. SEQ ID NO: 1 is 20,519 nucleotides in length. SEQ ID NO: 78 of Nandabalan is less than 120 nucleotides downstream from PS1. Several has not been specifically defined by the specification. Given the size of SEQ ID NO: 1 and the relativeness of "several," the examiner has deemed that 120 nucleotides downstream from PS1 encompasses 120 nucleotides downstream such that SEQ ID NO: 78 is encompassed by the instant claims.

With respect to Claim 20, the claim has been amended to over come the previous rejection. As suggested by the response, "the complement" is directed to the complement over the full length.

With respect to Claim 28, the claims has been amended to overcome the rejection with respect to the known PS sites.

Thus for the reasons above and those already of record, the rejection is maintained.

6. Claims 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauptmann et al. (Genbank Accession Number A29098, July 1995).

Hauptmann et al. (herein referred to as Hauptmann) teaches a nucleic acid for TNF-receptor. The nucleic acid of Hauptmann is an oligonucleotide which can detect a polymorphism at PS 17 and is allele-specific (limitations of Claim 14). The nucleic acid of Hauptmann contains SEQ ID NO: 9 (limitations of Claim 15). Moreover, the nucleic

acid of Hauptmann is extendable (limitations of Claim 16) and comprises SEQ ID NO: 35, for example (limitation of Claim 17). The nucleic acid of Hauptmann is extendable because the final nucleotide is not a blocking nucleotide. Thus, the nucleic acid is capable of primer extension. Therefore because Hauptmann teaches every element of the claims, Hauptmann anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts that Claim 13 has been amended to have a maximum length of about 100 nucleotides. This argument has been reviewed but is not convincing because the claim is directed to an oligonucleotide having 15 to about 100 nucleotides. Having is open claim language, like comprising. Thus, the claim is drawn to an isolated oligonucleotide comprising 100 nucleotides. The nucleic acid of Hauptmann comprises 100 nucleotides, namely 1368 nucleotides.

Moreover, as described in the new 112/2nd rejection below, terminating is broadly interpreted to mean at the 3' end, rather than the sequence terminates in SEQ ID NO: 35. Thus for the reasons above and those already of record, the rejection is maintained.

7. Claims 13-14, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Prashad et al. (WO 94/02500, February 3, 1994).

Prashad teaches a nucleic acid oligonucleotide for detecting chromosomal translocations. The oligonucleotide comprises SEQ ID NO: 27. The oligonucleotide specifically hybridizes to an alleles of the TNFRSF1A gene at a region containing the polymorphic site. The nucleic acid of Prashad would hybridize to a region, namely

upstream of exon 1 (limitations of Claim 14). SEQ ID NO: 47 of Prashad is a primer extension oligonucleotides comprising SEQ ID NO: 27 (limitations of Claim 16). Therefore because Prashad teaches every element of the claims, Prashad anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts Claim 13 has been amended to require that the oligonucleotide specifically hybridizes to an allele of the selected polymorphic site. This argument has been reviewed but is not convincing because the sequence of Prashad would hybridize to "an allele" of the polymorphic site. The claim does not require that the oligonucleotide comprises one of two different allele within the sequence, but rather requires that the oligonucleotide "specifically hybridizes to an allele." Thus, the claims may encompass any nucleotide at the polymorphic site. Furthermore, specifically hybridizes does not require any particular conditions for hybridization, does not require any particular requirement that the oligonucleotide remains hybridized for any length of time, etc. Thus, under low stringency conditions, the oligonucleotide of Prashad with 14/24 matches would specifically hybridize to a region of SEQ ID NO: 1. Thus for the reasons above and those already of record, the rejection is maintained.

8. Claims 13-14, 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Brewer et al (WO 97/31011, August 1997).

Brewer et al. (herein referred to as Brewer) teaches a nucleic acid oligonucleotide which comprises SEQ ID NO: 26. The nucleic acid is an oligonucleotide which is capable of an extension reaction (limitations of Claims 16-17). The nucleic acid of Brewer would hybridize to a region, namely upstream of exon 1 (limitations of Claim 14). Therefore because Brewer teaches every element of the claims, Brewer anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts Claim 13 has been amended to require that the oligonucleotide specifically hybridizes to an allele of the selected polymorphic site. This argument has been reviewed but is not convincing because the sequence of Brewer would hybridize to "an allele" of the polymorphic site. The claim does not require that the oligonucleotide comprises one of two different allele within the sequence, but rather requires that the oligonucleotide "specifically hybridizes to an allele." Thus, the claims may encompass any nucleotide at the polymorphic site. Furthermore, specifically hybridizes does not require any particular conditions for hybridization, does not require any particular requirement that the oligonucleotide remains hybridized for any length of time, etc. Thus, under low stringency conditions, the oligonucleotide of Brewer with 15/21 matches would specifically hybridize to a region of SEQ ID NO: 1. It is noted that the 5' terminus comprises SE QID NO: 26. Thus for the reasons above and those already of record, the rejection is maintained.

9. Claims 13-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Weiss (Genbank Accession Number AZ953340, April 2001).

Weiss teaches a nucleotide sequence which comprises SEQ ID NO: 7 (limitations of Claim 15). The nucleic acid is 24 nucleotides in length.

Weiss Sequence: AATATGCTCTGCCTGCTCCTCTAA

SEQ ID NO: 7: CTCTGCCYGCTCCTC

The nucleic acid is an oligonucleotide which is capable of an extension reaction (limitations of Claims 16-17). The nucleic acid of Weiss would hybridize to an allele of PS 14 (limitations of Claim 14). Therefore because Weiss teaches every element of the claims, Weiss anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US Patent 5,474,796, December 12, 1995) in view of Ahern (The Scientist, Vol 9, No. 15, page 20, July 1995).

Brennan teaches oligonucleotides having 10 nucleotides each (10-mers). The oligonucleotides represent every possible permutation of the 10-mer oligonucleotide. Therefore, Brennan teaches every possible 10-mer nucleic acid. Claim 13 is drawn to an isolated oligonucleotide designed to detect a polymorphism. Since Brennan teaches every possible 10-mer oligonucleotide, Brennan teaches an array of different nucleotides which would achieve the function of detecting a polymorphism. The claims does not provide any length limitation or other structural features. Claim 14 is directed to an oligonucleotide which is allele specific and hybridizes to a region containing the polymorphism. The genus of oligonucleotides which is encompassed by the claim significantly overlaps the genus of Brennan. Claims 16 and 17 are directed to primers which comprise a nucleotide sequence of 10 nucleotides, namely SEQ ID NO: 25-38. Brennan teaches each of these oligonucleotides.

Brennan does not specifically teaches packaging necessary reagents into a kit.

However, Ahern teaches reagent kits offer scientists good return on investment. Ahern teaches kits save time and money because the kits already comes prepared.

Therefore, it would have been **prima facie** obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Brennan with the teachings of Ahern to incorporate the necessary reagents into a packaged kit. The ordinary artisan would have been motivated to have packaged the primers, probes, and reagents of Brennan into a kit, as taught by Ahern for the express purpose of saving time and money.

Response to Arguments

The response traverses the rejection. The response asserts that Brennan and Ahern do not provide motivation to select a set of oligonucleotides from the million possible 10-mers that are designed to haplotype the 7 specific polymorphic sites, which were unknown prior to "applicants disclosure" and to combine such oligonucleotides into a kit. This argument has been reviewed but is not convincing because the claim is drawn to a kit which comprises a set of oligonucleotides. The millions probes of Brennan are encompassed by the instant claims. The claims do not require a set of 7 oligonucleotides, but rather are open to additional components. Furthermore, the intended use of the claims do not render the product claim non-obvious.

With respect to applicant's argument directed to expectation of success, the claim is drawn to a product claim. The product is directed to a set of oligonucleotides. The structural aspect of the 10-mers would function as a set of oligonucleotides. Thus for the reasons above and those already of record, the rejection is maintained.

Allowable Subject Matter

12. The prior art does not teach a nucleic acid comprising nucleotides 2920-4210, 11417-12926 and 14634-16768 of SEQ ID NO: 43 (limitations of Claim 20, in part). Moreover, any combination of isogene nucleic acids comprising the nucleic acid would be free of the art (i.e. Claim 34, 43). Therefore Claims 20-21, 35 if limited to SEQ ID NO: 43 would be allowable over the art.

13. Claims 20-21, 34, 35 are objected to as containing non-elected subject matter.

14. Claims 20-21, 25, 34-35, 44-45 each contain allowable subject matter.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 6:00 a.m. to 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (571)272-0507

J. Goldberg

Jeanine Goldberg
Patent Examiner
March 15, 2004